

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH)	
AND MANUFACTURERS OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	D. Me. C.A. No. 00-157-B-H
)	
JOHN R. NICHOLAS, in his official)	D.R.I. C.A. No. 04-161-S
capacity as Commissioner of the)	
Department of Human Services for)	
the State of Maine, and)	
G. STEVEN ROWE, in his official)	
capacity as Attorney General)	
for the State of Maine,)	
)	
Defendants.)	

DECISION AND ORDER

WILLIAM E. SMITH, United States District Judge.*

I. Introduction

This case involves an effort by the State of Maine to leverage its market power as a major purchaser of pharmaceuticals (in its role as administrator of the Medicaid program in Maine), to force the suppliers of these drugs to lower their prices for non-Medicaid eligible (but nevertheless quite poor) citizens of Maine.

This case has a considerable history. In 2000, the State of Maine ("the State" or "Maine") developed a plan to address the difficult problem created by the spiraling costs of prescription drugs, and the burden placed upon its poor citizens as a result of

* Of the District of Rhode Island, sitting by designation.

these high costs.¹ Passage of Maine Rx precipitated this litigation, which began before Judge D. Brock Hornby in the District Court of Maine. After Judge Hornby issued an injunction preventing implementation of Maine Rx, the case worked its way up to the United States Supreme Court. Ultimately the Supreme Court, affirming the First Circuit, reversed the injunction and remanded the case to the District Court for further proceedings. The case has been transferred to this writer as a result of the recusal of Judge Hornby and the other judges in the District of Maine.

In its review of the case, the Supreme Court issued five widely divergent opinions. Subsequent to the Court's ruling, the State substantially revised Maine Rx. Thus, the plan this Court now has before it for review on the present motions is not the same plan that the Supreme Court so painstakingly examined. As a result of the changes to Maine Rx, the State now contends in its Motion to Dismiss that the case is no longer ripe for review. The Plaintiff -- Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association representing manufacturers that account for more than seventy-five percent of brand name drug sales in the United States -- in contrast, takes its cue from the concurring opinion of Justice Breyer and moves this Court to send the question

¹ The plan was originally entitled the "Maine Rx Program." In 2001, as will be discussed in more detail below, the plan was amended significantly and renamed the "Maine Rx Plus Program." This Court will refer to these programs generically as "the Plan," and specifically as "Maine Rx" or "Maine Rx Plus."

whether Maine Rx Plus is consistent with the requirements of the Medicaid statute to the Secretary of the U.S. Department of Health and Human Services ("the Secretary" or "HHS"). While the history of the case is long and tortured the motions before this Court can be disposed of in straight-forward fashion: The question at the heart of the matter is whether PhRMA's claim that the Maine Rx Plus Program is preempted by federal law is ripe for review at this time. This question must be examined through the prism of both the statutory and regulatory framework of the Medicaid Act, as well as the opinions of the Supreme Court Justices. In the end, it is quite clear that PhRMA's claim is not ripe for review and must be dismissed.

II. Background

A. Medicaid Generally

"In response to increasing Medicaid expenditures for prescription drugs, Congress enacted a cost-saving measure in 1990 that requires drug companies to pay rebates to States on their Medicaid purchases." Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 649 (2003) (internal footnote omitted). "Over the last several years, state legislatures have enacted supplemental rebate programs to achieve additional cost savings on Medicaid purchases as well as for purchases made by other needy citizens." Id. In negotiating rebates with the pharmaceutical companies, one of the negotiating tools statutorily available to state government is the

use of a "prior authorization" scheme.² When a particular drug is subject to prior authorization, before a doctor can prescribe that

² The concept of prior authorization, which began as a practice in some states, eventually was codified into federal law, as the Court explained in Walsh:

Prior to 1990, the Medicaid statute did not specifically address outpatient prescription drug coverage. The Secretary's regulations and guidelines "set the upper limits on each State's aggregate expenditures for drugs." Under plans approved by the Secretary, some States designed and administered their own formularies, listing drugs that they would cover. States also employed "prior authorization programs" that required approval by a state agency to qualify a doctor's prescription for reimbursement. . . . These programs were not specifically governed by any federal law or regulations, but rather were made part of the State Medicaid plans and approved by the Secretary because they aided in controlling Medicaid costs.

Congress effectively ratified the Secretary's practice of approving state plans containing prior authorization requirements when it created its rebate program in an amendment contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990). The new program had two basic parts. First, it imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary or, if authorized by the Secretary, with individual States, to provide rebates on their Medicaid sales of outpatient prescription drugs. . . .

Second, once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act

Most relevant to this case, Congress allowed States "as a condition of coverage or payment for a covered outpatient drug," to require approval of the drug before it is dispensed. Thus, under OBRA 1990, . . . "[a] State may subject to prior authorization any covered outpatient drug [subject to certain conditions]."

538 U.S. at 651-53 (internal footnotes and citations omitted).

drug to a Medicaid recipient and be assured the recipient will receive the Medicaid discount, the doctor must receive prior authorization from the appropriate government representative. Because this imposes an additional hurdle that stands between the pharmaceutical company and its potential customer, and given that there are usually alternative drugs available that doctors may prescribe that are not subject to a prior authorization scheme, pharmaceutical companies are anxious to avoid having their drugs subjected to such prior authorization schemes.³

B. The Original Maine Plan ("Maine Rx")

The right to negotiate rebates, in conjunction with prior authorization schemes, provides states with an effective tool to leverage their purchasing power in the pharmaceutical market. During the summer of 2000, Maine enacted its Maine Rx prescription

³ This sentiment was expressed in an affidavit submitted on behalf of PhRMA and quoted by the Supreme Court in Walsh:

Imposition of a prior authorization [(PA)] requirement with respect to a particular drug severely curtails access to the drug for covered patients and sharply reduces the drug's market share and sales, as the PA causes a shift of patients to competing drugs of other manufacturers that are not subject to a PA. Because a PA imposes additional procedural burdens on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it, the effect of a PA is to diminish the manufacturer's goodwill that helped foster demand for its drug over competing drugs produced by other manufacturers, and to shift physician and patient loyalty to those competing drugs, perhaps permanently.

538 U.S. at 656 (quoting affidavit of George Bilyk of Janssen Pharmaceutica, Inc.).

drug plan, seeking to do exactly that in an effort to obtain less expensive prescription drugs for a greater number of its citizens. 2000 Me. Legis. Serv. 786 (S.P. 1026) (L.D. 2599); see Timothy Stoltzfus Jost, Pharmaceutical Research and Manufacturers of America v. Walsh: The Supreme Court Allows the States to Proceed with Expanding Access to Drugs, 4 Yale J. Health Pol'y, L. & Ethics 69, 77 (2004) ("Maine's program, at issue in Walsh, attempted to use this lever -- the threat of requiring prior authorization -- to make discounts available to all residents of the state who lacked insurance coverage for drugs, regardless of income."). The Maine Rx Program had three primary provisions: (1) it prohibited profiteering and excessive pricing by drug manufacturers and created extensive civil penalties for violations; (2) it prohibited manufacturers from altering their distribution schemes so as to avoid the application of the Maine law; and (3) it ordered the Maine Commissioner of Human Services to negotiate with the drug manufacturers to provide a rebate which would apply every time an uninsured Maine citizen bought a prescription at a pharmacy in Maine. In order to persuade manufacturers to cooperate in the rebate program, the State created two penalties for failure to negotiate rebates: first, the names of those manufacturers that did not participate were to be made public; and second, the drugs of the non-participating manufacturers would be put on a list of

drugs requiring prior authorization before they could be approved for Medicaid reimbursement.

PhRMA challenged the Maine Rx Program on two grounds: that it violated the Commerce Clause and was preempted by the federal Medicaid statute. PhRMA sought an injunction against the implementation of Maine Rx. Judge Hornby, after a hearing, concluded that the anti-profiteering provision and the rebate provision violated the Commerce Clause; further, because Maine could identify no Medicaid-related purpose in the prior authorization requirement, Maine Rx was preempted under the Supremacy Clause. The Court thus granted a preliminary injunction to PhRMA, ordering Maine not to "penaliz[e] manufacturers, by placing their drugs on prior listing status, for refusing to negotiate or to pay a rebate to Maine's Rx program," and prohibiting Maine "from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine." Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Servs., No. Civ. 00-157-B-H, 2000 WL 34290605, at *7 (D. Me. Oct. 26, 2000), rev'd, 249 F.3d 66 (1st Cir. 2001), aff'd, 538 U.S. 644 (2003).

On appeal, the First Circuit reversed. Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66 (1st Cir. 2001).⁴ Because

⁴ Maine did not appeal the District Court's holding that the anti-profiteering provision was unconstitutional. Concannon, 249 F.3d at 82 n.10. That injunction remains in place, and is made

affirming “the district court’s preemption holding . . . would invalidate the Act as to all distributors . . . and would obviate the need to address the Commerce Clause,” the court turned to the preemption issue first.⁵ Id. at 74. It concluded, however, that there was “no conflict between the Maine Act and Medicaid’s structure and purpose,” and that, in any event, there was not enough evidence in the record for PhRMA to meet the difficult burden, on a facial challenge, of showing that Medicaid recipients would in fact be harmed by the Maine Rx Program. Id. at 75, 77. The court thus held “that the Maine Act [wa]s not preempted by the Medicaid statute.” Id. at 79.

Turning next to the dormant Commerce Clause analysis, the court held that Maine Rx did not constitute a per se violation of the dormant Commerce Clause because on its face “the regulation only applies to in-state activities.” Id. at 82; see also id. at 79 (“[A] state statute is a per se violation of the Commerce Clause when it has an ‘extraterritorial reach.’”) (quoting Healy v. Beer Inst., Inc., 491 U.S. 324, 336 (1989)). Furthermore, because the local benefits of the Maine Rx Program (i.e., increasing access to prescription drugs for Maine citizens) appeared to outweigh its

permanent in this Order.

⁵ Only the prior authorization component of the statute’s penalty provision was challenged. The public identification component was not challenged, and the court did not address it. Concannon, 249 F.3d at 74 n.4.

burden on interstate commerce (i.e., the loss of profits incurred by manufacturers), the court found that the Maine Rx Program did not on its face impose an unconstitutional burden on interstate commerce under the Pike balancing test. Concannon, 249 F.3d at 84; see Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) ("Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."). Thus, while finding that it was "a close case," the court concluded that "the State of Maine should [not] be prohibited from putting the [Maine Rx Program] into play." Concannon, 249 F.3d at 85.

C. The Supreme Court Opinion

The United States Supreme Court granted certiorari, affirmed the First Circuit, and issued five separate opinions on the Maine plan. Walsh, 538 U.S. 644.⁶ First, the Court affirmed the First

⁶ For purposes of deciding the present motion, it is not necessary to decipher each opinion in great detail, nor evaluate every nuance regarding what the Justices may be saying with respect to the larger issues potentially involved when states embark on plans such as the one at issue in this case. Moreover, that task is not always an easy one. See generally Metromedia, Inc. v. San Diego, 453 U.S. 490, 569 (1981) (Rehnquist, J., dissenting) (stating, in response to five separate opinions being issued in that case, that it was "a genuine misfortune to have the Court's treatment of the subject be a virtual Tower of Babel, from which no definitive principles can be clearly drawn"). Deconstruction of the Court's myriad opinions for what they may portend for the future of similar programs is a task better left to commentators.

Circuit as to the Commerce Clause claim, stating that "the Maine Act does not regulate the price of any out-of-state transaction," and "will not impose a disparate burden on any competitors."⁷ Id. at 670. Second, a plurality of the Court concluded that the Maine Rx Program was not preempted by the Medicaid statute because it was not clear that the Plan failed to serve a Medicaid purpose as required by the Medicaid Act. Id. at 662-63 (opinion of Stevens, J.). The plurality argued that, on its face, the Plan could be said to serve three Medicaid-related goals ("provid[ing] medical benefits to persons who can be described as 'medically needy'"; potentially reducing future Medicaid expenses "by enabling some borderline aged and infirm persons better access to prescription drugs earlier"; and "[a]voiding unnecessary costs in the administration of [Maine]'s Medicaid program" via its scheme of prior authorization). The plurality suggested that in serving

See Stoltzfus Jost, supra, at 82 (setting out three conclusions that "emerge from the multiple opinions when read together"); Lynsey Mitchel, Maine's Battle in America's Other Drug War: Pharmaceutical Research and Manufacturers of America v. Walsh, 24 J. Nat'l A. Admin. L. Judges 81, 97-108 (2004) (reviewing various parts of Supreme Court's opinion). For the task at hand, a brief overview of the opinion will suffice.

⁷ Although this case generated five separate opinions, all nine Justices agreed with the holding of the First Circuit that the District Court erred in concluding that the Maine Rx Plan violated the dormant Commerce Clause. Id. at 669-70; id. at 670 (Breyer, J., concurring); id. at 674 (Scalia, J., concurring); id. at 675 (Thomas, J., concurring); id. at 684 (O'Connor, J., concurring in part and dissenting in part).

these goals the Plan did not "severely curtail[] Medicaid recipients' access to prescription drugs." Id. at 663-65.

However, the plurality noted that on remand the District Court might well conclude that Maine Rx does not serve a Medicaid purpose. Id. at 660 ("[N]o matter how we answer the question whether [PhRMA]'s showing was sufficient to support the injunction, further proceedings in this case may lead to a contrary result."). The plurality opinion also noted that the view of the Secretary of HHS would likely be relevant to this determination. Id. ("Moreover, there is also a possibility that the Secretary may view the Maine Rx Program as an amendment to its Medicaid Plan that requires his approval before it becomes effective."). Furthermore, the determination of HHS would be entitled to a presumption of validity. Id. at 661 ("In such event, the Secretary's ruling would be presumptively valid."). Moreover, while the government argued, as an amicus, that Maine Rx violated the Medicaid Act and was therefore preempted, the plurality noted this position might well change with the further development of the facts. Id. The plurality took pains to point out, however, that while HHS "is likely to take some action" regarding the Plan, the question whether HHS must approve the Plan, or whether Maine must request review, was not before the Court. Id. at 668 ("We again reiterate that the question whether the Secretary's approval must be sought

before [the] Maine Rx Program may go into effect is not before us.").

Justice Breyer wrote a concurring opinion in which he argued that the views of HHS were critical to the evaluation of the appropriateness of Maine's prior authorization program. He asserted that, since "proper determination of the pre-emption question will demand a more careful balancing of Medicaid-related harms and benefits," and since "[t]he Department of Health and Human Services (HHS) . . . is better able than a court to assemble relevant facts . . . and to make relevant predictions," the District Court should utilize "the legal doctrine of 'primary jurisdiction'" to refer the question of costs and benefits of the Maine Rx Program to the Secretary of HHS, upon remand. Id. at 672-73 (Breyer, J., concurring). Justice Breyer viewed the role of HHS as critical to this Court's resolution of the ultimate question whether Maine Rx served a Medicaid purpose. Moreover, Justice Breyer, like the plurality, noted that a determination by HHS would be presumptively valid and would be entitled to deference. Id. at 672 ("[T]he law grants significant weight to any legal conclusion by the Secretary as to whether a program such as Maine's is consistent with Medicaid's objectives.") (citing Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984)).

Justice Scalia authored a short concurring opinion in which he argued, as to the preemption claim, that the proper "remedy for the

State's failure to comply with the obligations it has agreed to undertake under the Medicaid Act is set forth in the Act itself: termination of funding by the Secretary of the Department of Health and Human Services." Id. at 675 (Scalia, J., concurring) (internal citations omitted). Thus, PhRMA "must seek enforcement of the Medicaid conditions by [HHS] -- and may seek and obtain relief in the courts only when the denial of enforcement is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Id. (quoting 5 U.S.C. § 706(2)(A)).⁸

Justice Thomas wrote a lengthy concurrence, in which he stated that he did "not believe that 'further proceedings in this case may lead to a contrary result'" (as had been suggested by the plurality), and that "[i]t is clear from the text of the Medicaid Act and the Constitution that petitioner's pre-emption and negative Commerce Clause claims are without merit." Id. at 675 (Thomas, J., concurring). Justice Thomas pointed out that "[t]he Medicaid Act represents a delicate balance Congress struck between competing interests -- care and cost, mandates and flexibility, oversight and discretion." Id. at 676. This "compromise[] embodied in the Medicaid Act," moreover, highlights "the impossibility of defining 'purposes' in complex statutes at such a high level of abstraction

⁸ Justice Scalia's opinion does not make clear how PhRMA is supposed to "seek enforcement of the Medicaid conditions" by HHS. Resolution of this question, however, is not essential to this Court's ultimate determination of the matter before it.

and the concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others." Id. at 678. Furthermore, Justice Thomas echoed Justice Scalia in pointing out that "State plans that do not meet [the Medicaid Act's] requirements are to be defunded by the Secretary -- they are not void under the Supremacy Clause." Id. at 680 n.3. To hold otherwise would moot the Secretary's "pre-emptive authority," explicitly delegated by Congress. Id. at 679. Finally, Justice Thomas analogized the present case to a third-party beneficiary claim. He pointed out that "[t]he Court has stated that Spending Clause legislation 'is much in the nature of a contract,'" and thus there are "serious questions as to whether third parties [like PhRMA] may sue to enforce Spending Clause legislation -- through pre-emption or otherwise." Id. at 682-83 (quoting Pennhurst State Sch. and Hosp. v. Halderman, 451 U.S. 1, 17 (1981)).

Justice O'Connor, joined by Chief Justice Rehnquist and Justice Kennedy, dissented in part. Id. at 684. The dissenters agreed with the plurality that under the Supremacy Clause, "States may not impose on Medicaid beneficiaries the burdens of prior authorization in the absence of a countervailing Medicaid purpose," but disagreed "that the District Court abused its discretion in enjoining [Maine] from imposing prior authorization." Id. The dissenters apparently did not view the role of HHS as central to the determination whether the Plan served a Medicaid purpose,

believing the District Court could (and did) properly make that assessment.

D. The New Maine Plan ("Maine Rx Plus")

Having successfully defeated PhRMA's effort to sustain the preliminary injunction, Maine nevertheless chose to amend the Maine Rx Program for reasons that are not entirely clear from the record, but which may have been intended to respond to some of the concerns raised by PhRMA in its original Complaint, see Meg Haskell, Maine Rx Plus ready to roll: 275,000 eligible for discount drugs, Bangor Daily News, Jan. 14, 2004, at A1 ("Given the go-ahead, the state in June announced the fine-tuning of the program in response to some of PhRMA's concerns and renamed it Maine Rx Plus."). Maine Rx was amended to provide that prior authorization shall only be imposed "to the extent [DHS] determines it is appropriate to do so in order to encourage manufacturer and labeler participation in the program and so long as the additional prior authorization requirements remain consistent with the goals of the MaineCare program and the requirements of the federal Social Security Act." Me. Rev. Stat. Ann. tit. 22, § 2681(7) (2004). PhRMA, in response, amended its Complaint to remove its Commerce Clause challenges to Maine Rx Plus's rebate provisions, and add a Supremacy Clause challenge alleging Maine was required by federal law to submit its Plan to HHS for review. (Pl.'s Am. Compl. at 11.) Following the suggestion of Justice Breyer, PhRMA then filed a Motion for Primary

Jurisdiction Referral, requesting this Court to refer to HHS the question "whether the Maine Rx Program is consistent with the federal Medicaid program." (Pl.'s Mot. for Prim. Jurisd. Ref.) Defendants responded with a Motion to Dismiss Counts I, II, IV and VI.⁹

III. Analysis

A. Standard of Review

Pursuant to Federal Rule of Civil Procedure 12(b)(6), this Court must determine whether the Complaint states any claim upon which relief could be granted. See Fed. R. Civ. P. 12(b)(6). In so doing, the Court accepts all well-pleaded factual assertions as true and draws all reasonable inferences from those assertions in the Plaintiff's favor. See Aybar v. Crispin-Reyes, 118 F.3d 10, 13 (1st Cir. 1997). A plaintiff is "required to set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal

⁹ Specifically, the claims in PhRMA's Amended Complaint are as follows: Count I alleges that the prior authorization provision of Maine Rx Plus violates the Supremacy Clause; Count II alleges that this same prior authorization provision constitutes a material change to the State's Medicaid program requiring approval by HHS and that failure to obtain such approval violates the Supremacy Clause; Count III alleges that the anti-profiteering provisions of Maine Rx Plus violate the Commerce Clause; Count IV alleges that the anti-retaliation provision of Maine Rx Plus violates the Commerce Clause; and Count VI brings claims against the Commissioner of DHS and the Maine Attorney General under 42 U.S.C. § 1983. Count V of the original Complaint was dropped and not replaced. Defendants do not challenge the preliminary injunction that remains in effect as to Count III. (Defs.' Mot. to Dismiss at 1.)

theory." Gooley v. Mobil Oil Corp., 851 F.2d 513, 515 (1st Cir. 1988).

B. Counts I & II -- Prior Authorization, the Supremacy Clause, and Ripeness

PhRMA argues that the prior authorization scheme employed by the Maine Rx Plus Program violates the Supremacy Clause because it (1) harms Medicaid beneficiaries, and (2) constitutes a material change requiring HHS approval, which approval has not been sought. Maine contends that PhRMA's claim is not ripe for review because the Maine Rx Plus prior authorization scheme has not yet been implemented, and Maine has no present plans to do so. Specifically, Maine points to the amendment in Maine Rx Plus, which changed a mandatory prior authorization scheme, see 2003 Me. Laws 494, § 5 (reciting text of original statute: DHS "shall impose prior authorization requirements"), to a discretionary one, see Me. Rev. Stat. Ann. tit. 22, § 2681(7) (2004) (adding the words: "to the extent the department determines it is appropriate"). In addition, Maine points to the rules promulgated by DHS for implementation of the revised program, which set forth that the incentive for manufacturers to enter into rebate agreements is that they will receive a "preferred designation" in Maine Rx Plus. Code Me. R. § 3.08(C) (2004). The Comments of DHS to these rules elaborate that: "The only consequence provided by the rule for [manufacturers that refuse to enter into rebate agreements] is that they may not earn a "preferred" designation in Maine Rx

Plus [T]he rule does not provide for the use of prior authorization for drugs reimbursed through Maine Rx Plus." (Defs.' Mot. to Dismiss, Ex. B (Summary of Comments, Chapter 104, Section 3, Maine Rx Plus Benefit, at 9) (emphasis in original).) Furthermore, the letters sent to manufacturers seeking to negotiate a rebate make no mention of prior authorization. (Defs.' Mot. to Dismiss, Ex. C (Letter from Walsh to Pharmaceutical Manufacturer of 3/11/04).) Finally, Maine references representations it has made orally and in writing to this Court to the effect that it would not seek to implement the prior authorization scheme before first seeking HHS approval and receiving a decision thereon.¹⁰ (Defs.' Mot. to Dismiss at 7.)

In effect Maine argues that by enacting Maine Rx Plus it has rendered PhRMA's Complaint unripe. Some courts have rejected similar attempts by parties to render a case unripe. See Malama Makua v. Rumsfeld, 136 F. Supp. 2d 1155, 1161 (D. Haw. 2001) ("Ripeness is an element of jurisdiction and is measured at the

¹⁰ PhRMA points out that there is nothing binding about these representations. This is true. Thus, the Court may not accord any weight to these representations, but sets them forth in the interest of completeness. It bears noting that at oral argument the Court inquired as to why the State has not bound itself to this representation by statute or regulation. The State replied that its "federalism" concerns have precluded it from doing so. (Tr. at 14.) Whatever the motivation, the impact for purposes of this motion is simply that the State retains the authority to put prior authorization into place, without first seeking approval of HHS, at any time it chooses. Its representations to the contrary do nothing to change this.

time an action is instituted; ripeness is not a moving target affected by a defendant's action."). However, in a declaratory judgment action such as this, the controversy must remain ripe throughout the course of the proceeding. See Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974) ("The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed."); see also Travelers Ins. Co. v. Obusek, 72 F.3d 1148, 1154 (3d Cir. 1995) ("[R]ipeness requires that the threat of future harm must remain 'real and immediate' throughout the course of the litigation.") (quoting Salvation Army v. Dep't of Cmty. Affairs, 919 F.2d 183, 192 (3d Cir.1990)).

The basic rationale of the ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99, 105 (1977). "The problem is best seen in a twofold aspect, requiring [the Court] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Id. at 149.

"Under the 'fitness for review' inquiry, [the Court should] consider whether the issue presented is purely legal, as opposed to factual, and the degree to which any challenged agency action is final." W.R. Grace & Co. v. United States Env'tl. Prot. Agency, 959 F.2d 360, 364 (1st Cir. 1992). "Perhaps the most important consideration in determining whether a claim is ripe for adjudication is the extent to which 'the claim involves uncertain and contingent events that may not occur as anticipated, or indeed may not occur at all.'" Lincoln House, Inc. v. Dupre, 903 F.2d 845, 847 (1st Cir. 1990) (quoting 13A Wright & Miller, Federal Practice and Procedure § 3532.2, at 141 (1984)).

Determining whether Maine's prior authorization scheme impermissibly conflicts with Medicaid would involve a balancing of the impediments Maine's prior authorization scheme imposes on Medicaid recipients' ability to obtain prescription drugs with the benefit to Medicaid as a whole. See Walsh, 538 U.S. at 664-65 (opinion of Stevens, J.) ("The fact that the Maine Rx Program may serve Medicaid-related purposes . . . would not provide a sufficient basis for upholding the program if it severely curtailed Medicaid recipients' access to prescription drugs."); see also id. at 672 (Breyer, J., concurring) ("proper determination of the pre-emption question will demand a more careful balancing of Medicaid-related harms and benefits"). Determination of this question would require a careful and detailed factual inquiry.

Maine argues that where no prior authorization scheme has been implemented, there are no facts for this Court to use to make the assessment. PhRMA counters that "no further administrative action or clarification is necessary or required for the Court to determine, or the U.S. Department of Health and Human Services ("HHS") to assess, whether the [Maine] Program is consistent with or preempted by the Medicaid statute." (Pl.'s Opp. at 2.) PhRMA bases this argument in part on the fact that "HHS has never permitted a state to amend its Medicaid plan to extend drug benefits to non-Medicaid individuals whose incomes exceed 200% of the federal poverty level ('FPL')";¹¹ thus Maine's program, "which uses Medicaid leverage to compel manufacturers to make payments to fund non-Medicaid benefits for individuals with incomes up to 350% of the FPL, see Me. Rev. Stat. Ann. tit. 22 § 2681(2) -- is presumptively illegal." (Pl.'s Opp. at 2.)

"From the agency's perspective, premature review not only can deprive the agency of the opportunity to refine, revise or clarify the . . . matter at issue, but it also can deprive it of the opportunity to resolve the underlying controversy on other grounds, thus . . . avoiding the need for court proceedings." Roosevelt

¹¹ But cf. Brief for the United States as Amicus Curiae at 24-25, Walsh, 538 U.S. 644 ("[O]n January 18, 2001, the Secretary approved a demonstration project for Maine . . . consist[ing] of two components: (1) a "Low Cost Drugs for the Elderly or Disabled" (DEL) program, . . . and (2) a non-DEL component, under which the State pays two percent of the costs of non-DEL drugs purchased by persons with incomes below 300% of the federal poverty level.").

Campobello Int'l Park Comm'n v. United States Env'tl. Prot. Agency, 684 F.2d 1034, 1040 (1st Cir. 1982). At oral argument, Maine's counsel presented examples of statistics Maine may wish to gather on topics such as population fluctuation and the impact of other programs.¹² Maine may choose to revise the 350% FPL threshold (Defs.' Reply at 3.); it may delay implementation pending negotiations with manufacturers; or it may choose to forego implementation altogether for any number of reasons. Thus, the challenged program is simply too embryonic to determine just what

¹² Maine's counsel stated:

For example, Maine is a large, rural state without a lot of population. In addition, Maine is subject to seasonal fluctuations of employment; tourism in the summer, fishing, things of that nature.

The 200 percent versus 350 percent, the number of people that flow back and forth above that 200 percent on a yearly basis in Maine may be such that the Secretary concludes after we present the statistics that [350% is] appropriate in the State of Maine.

Similarly, in the State of Maine we have a variety of programs which appear to be accepted even by PhRMA including [a] Drugs for the Elderly program. The Drugs for the Elderly program actually has more people in it than the Maine Rx Plus program has.

If one were to do a statistical analysis of the number of people who are presently on DEL or [the] Drugs for the Elderly program and who would also be in the Maine Rx Plus program in this 350 percent, the 200 to 350 percent, one might find that it's a very small number .

. . .

(Tr. at 22.)

its contours will be when and if it is finally implemented. Therefore, Count I is not ripe for review at this time.¹³

The same can be said for PhRMA's claim in Count II that Maine's prior authorization scheme constitutes a plan amendment requiring HHS approval -- which approval has not been obtained. Obtaining approval for a plan amendment is not easy. It requires considerable preparation and the presentation of evidence to the Secretary. See Brief for the United States as Amicus Curiae at 29, Walsh, 538 U.S. 644 ("The Secretary has informed State Medicaid Directors that in submitting a plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program.") (internal quotation marks omitted). Because the scheme may never be implemented, it would be premature to force Maine at this point to defend a program that has not yet been fully developed, let alone implemented. See Doe v. Bush, 323 F.3d 133,

¹³ PhRMA cites to the statute's use of the word "shall" at various points to argue that it is only "ostensibly" discretionary. (Pl.'s Opp. at 7-8 (citing portions of Maine statute stating that manufacturers "shall enter into a rebate agreement with [DHS]" and DHS "shall impose prior authorization requirements . . . in order to encourage manufacturer . . . participation in the [Maine Rx Plus] program").) However, the statute, as amended, clearly vests discretion with DHS to impose prior authorization only "to the extent the department determines it is appropriate." In light of the statute's use of this language (which explicitly vests authority to implement (or not) in DHS) and based upon the facts before the Court at this time, there can be little debate that the implementation of prior authorization under the amended statute is indeed discretionary.

138-39 (1st Cir. 2003) ("[T]hat the future event may never come to pass augurs against a finding of fitness.") (quoting McInnis-Misenor v. Me. Med. Ctr., 319 F.3d 63, 72 (1st Cir. 2003)).

PhRMA asserts its members will suffer great hardship if review is denied. See Rhode Island v. Narragansett Indian Tribe, 19 F.3d 685, 693 (1st Cir. 1994) ("The second part of the ripeness inquiry evoked by declaratory judgment actions is concerned with the hardship to the parties that would result from a refusal to consider granting relief."). Specifically, PhRMA argues its members will be placed squarely on the "horns of a dilemma," Stern v. United States Dist. Court for the Dist. of Mass., 214 F.3d 4, 11 (1st Cir. 2000), forced to choose between acceding to Maine's request for rebates or having their products subjected to prior authorization. It may be true that PhRMA's members have been invited into a high stakes game of public policy poker with the State of Maine and with each other. Will any member of PhRMA dare to thumb its nose at Maine and refuse to provide rebates? If this occurs, will others follow suit or will PhRMA's members turn on one another to gain a competitive advantage? Or, might a drug manufacturer simply refuse to sell its products in Maine? These are all difficult business decisions to be sure; but the prospect of making difficult business decisions in a competitive marketplace is not an injury for which one seeks redress in court. PhRMA complains that the State's carrot-and-hidden-stick approach is

unfair because “[a]t any moment, the State could, in its discretion, pull that stick out from behind its back and penalize manufacturers that have declined to pay the rebates demanded. . . . That Maine promises not to swing the prior authorization stick today does nothing to prevent the State from doing so tomorrow.” (Pl.’s Opp. at 12.) But the statute explicitly requires that prior authorization may be implemented only “as permitted by law” and in a manner “consistent with the goals of the MaineCare program and the requirements of the federal Social Security Act.” Me. Rev. Stat. Ann. tit. 22, § 2681(7) (2004). Since it is possible for Maine to implement its prior authorization without violating the law, this Court must assume it will until, in fact, it does not. If Maine uses the stick instead of the carrot, it must do so within, and as permitted by, the law. If Maine wields the prior authorization stick in an unlawful manner, as PhRMA fears and anticipates, PhRMA (and its members) surely know what to do about it.

PhRMA also presses the alternative formulation of the hardship prong of the ripeness analysis suggested by Judge Selya in Narragansett Indian Tribe, to induce this Court to take preemptive action against Maine: “Rather than asking, negatively, whether denying relief would impose hardship, courts will do well to ask, in a more positive vein, whether granting relief would serve a useful purpose, or, put another way, whether the sought-after

declaration would be of practical assistance in setting the underlying controversy to rest." Narragansett Indian Tribe, 19 F.3d at 693.

It is important, however, to recall that in Narragansett Indian Tribe the question squarely presented was whether the Indian Gaming Act applied to the settlement lands of the Narragansetts, and what, if any, jurisdiction the state and municipal governments retained over those settlement lands. Judge Selya, in presenting the hardship question in this manner took pains to point out that this formulation was no "radical departure" from the Supreme Court's holding in Abbott Laboratories or the First Circuit's own precedents. Narragansett Indian Tribe, 19 F.3d at 693. Moreover, as Judge Selya notes, the point of declaratory relief is to assist the parties in understanding their legal relationship. That need was acute in Narragansett Indian Tribe because the Narragansett Tribe, State of Rhode Island and local officials were attempting to negotiate a gaming compact pursuant to the Indian Gaming Act, but disagreed substantially on the fundamental question whether that Act applied to the settlement lands and whether the state and municipal governments retained jurisdiction (and if so, how much) over that land. Negotiations simply were impossible without the parties knowing the answer to these questions. There was no looming future event that would either offer further clarity or render the entire issue moot.

Here, the parties clearly understand their relationship to each other and they are engaging in arms-length dealings. The State's ability to utilize prior authorization is statutorily authorized. To be sure, it would make PhRMA's members' task in their negotiations much easier if they knew up-front whether Maine's prior authorization scheme would pass scrutiny if implemented, but this Court does not believe that this is the type of "useful purpose" or "practical assistance" Judge Selya had in mind when he authored his formulation. Moreover, the First Circuit has cautioned:

Especially when matters of great public moment are involved, declaratory judgments should not be pronounced unless the need is clear, not remote or speculative. . . .

[C]ourts should withhold declaratory relief as a matter of discretion if such redress is unlikely to palliate, or not needed to palliate, the fancied injury, especially when refraining from issuing a declaratory judgment avoids the premature adjudication of constitutional issues. . . .

[W]e believe that declaratory judgments concerning the constitutionality of government conduct will almost always be inappropriate when the constitutional issues are freighted with uncertainty and the underlying grievance can be remedied for the time being without gratuitous exploration of uncharted constitutional terrain.

El Dia, Inc. v. Hernandez Colon, 963 F.2d 488, 494 (1st Cir. 1992)
(internal quotation marks, alterations, and citations omitted).

PhRMA formally pleads that Maine has cleverly enacted an "unreviewable" statute that provides Maine all the leverage it is seeking in negotiating rebates from PhRMA's members while

insulating it from judicial scrutiny, and that unless this Court takes action there will be no opportunity to challenge the prior authorization scheme. But that is a mischaracterization of the situation. Whatever pressure PhRMA's members may be feeling at this time (and there is little record evidence on this point) likely results more from the competitiveness of the pharmaceutical industry than from anything Maine has done (or may do). It is not this Court's role to protect PhRMA's members from the marketplace. PhRMA's members remain free to refuse to grant a rebate to the State of Maine under the Maine Rx Plus Program. At that point, Maine may or may not attempt to subject the recalcitrant manufacturer to its prior authorization scheme. If it does, and PhRMA (or one of its members) believes the scheme is unconstitutional as implemented at that time, then PhRMA may reassert its challenge. If Maine decides to implement its prior authorization scheme, or returns to a scheme whereby prior authorization is no longer discretionary, PhRMA will be able to reassert its challenge as well. See Concannon, 249 F.3d at 78 ("This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement 'as applied.'") (emphasis added). Put simply, there are many possible scenarios which could develop with the implementation of Maine Rx Plus. PhRMA, its members, the State

of Maine, and HHS may, at the appropriate time, take whatever steps are called for depending on how the Maine Rx Plus program evolves.

Maine has not succeeded in creating an “unreviewable” statute, as PhRMA contends, for another reason: the statute remains subject to HHS review. Whatever disagreements the Justices had in evaluating Maine Rx, one thing is clear from reading the various opinions in Walsh: HHS has a significant role in determining whether Maine has overstepped its authority in enacting its Plan. See Walsh, 538 U.S. at 660 (opinion of Stevens, J.) (“[T]here is also a possibility that the Secretary may view the Maine Rx Program as an amendment to its Medicaid Plan that requires his approval before it becomes effective.”); id. at 672 (Breyer, J., concurring) (stating that views of Secretary “are highly relevant” and encouraging primary jurisdiction referral); id. at 675 (Scalia, J., concurring) (suggesting enforcement of Medicaid’s primacy is in HHS’s hands, and that “Petitioner must seek enforcement of the Medicaid conditions by [HHS]”); id. at 681 (Thomas, J., concurring) (“The Secretary is expressly charged with determining whether state plans comply with the numerous requirements of 42 U.S.C. §§ 1396a(a), 1396a(b), 1396c.”). In fact, the plurality in Walsh went so far as to say that “it appears that the Secretary is likely to take some action with respect to this program.” Id. at 668 (opinion of Stevens, J.). Thus, while Maine’s program is not reviewable by this Court at this time due to a lack of ripeness, it

is not thereby rendered unreviewable. It is, and remains, subject to review by HHS at the appropriate time. See id. at 672 (Breyer, J., concurring) ("Institutionally speaking, [HHS] is better able than a court to assemble relevant facts . . . and to make relevant predictions").¹⁴

C. Count IV -- The Anti-Retaliation Clause, the Commerce Clause, and Ripeness

PhRMA challenges § 2697(2)(D) of the Maine statute, which provides that "[a] manufacturer . . . engages in illegal profiteering if that manufacturer . . . [i]ntentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in [Maine] in retaliation for the provisions of this chapter." Illegal profiteering under the statute can result in civil suit and treble (as well as punitive) damages. Me. Rev. Stat. Ann. tit. 22, § 2697(2)(D) (2004). PhRMA argues that this provision is unconstitutional because it arguably "prohibits drug manufacturers from arranging their interstate distribution channels in response to the Maine Rx Statute," (Pl.'s Am. Compl. at 12), which violates the Commerce Clause. Because Maine has not enforced the statute, PhRMA must show a "'credible threat' of enforcement." Stern, 214 F.3d at 11 (quoting New Hampshire Right to Life Political Action Comm. v. Gardner, 99 F.3d 8, 14 (1st Cir. 1996)); see Rhode Island Ass'n of Realtors, Inc. v. Whitehouse, 199 F.3d

¹⁴ This Court takes no position regarding whether Maine Rx Plus is reviewable by HHS as it currently stands.

26, 33 (1st Cir. 1999) ("To establish ripeness in a pre-enforcement context, a party must have concrete plans to engage immediately (or nearly so) in an arguably proscribed activity.").

In ruling on PhRMA's Motion for Preliminary Injunction, Judge Hornby stated that:

[PhRMA] wants me to declare . . . that if the manufacturers merely alter their distribution channels out-of-state, they cannot be held liable under this provision. Although that seems to be a reasonable conclusion, it is unnecessary and inappropriate for me to rule at this time. . . . I have no specific actions by manufacturers on which to base such a ruling, and a Maine court might construe this portion of the statute in a narrow way that would avoid any constitutional issue.

PhRMA, 2000 WL 34290605, at *2. In this part of his opinion, Judge Hornby does not appear to have been making a determination that PhRMA's claim was not justiciable for the purposes of a preliminary injunction, but rather a holding more broadly that the claim was not ripe for review generally. In stating his position on this point, Judge Hornby cited Ernst & Young v. Depositors Econ. Prot. Corp., 45 F.3d 530 (1st Cir. 1995), for the proposition that "courts should avoid answering hypothetical questions." PhRMA, 2000 WL 34290605, at *2. In Ernst & Young, the First Circuit upheld a district court's dismissal of a declaratory judgment action on ripeness grounds. 45 F.3d at 535 ("In the first instance, the district court dismissed E & Y's action due to ripeness concerns. E & Y assigns error. We discern none.") (internal citation omitted); see also id. ("[A] court has no

alternative but to dismiss an unripe action."). Thus, while Judge Hornby did not explicitly dismiss the claim in his conclusion, since little has changed with respect to the basis for PhRMA's claim from then until now, this Court views his ruling as the law of the case to the effect that PhRMA's claim here is not ripe for review.

PhRMA continues to press the argument, however, and states that "no one disputes that the Maine Rx Plus Program raises manufacturers' costs of doing business in Maine." (Pl.'s Opp. at 15) Thus, continues PhRMA, "manufacturers might well [want to] alter their business practices in response to the Maine Rx Plus Program." (Id.) By way of example, PhRMA points specifically to one pharmaceutical manufacturer that apparently changed its distribution channels prior to the Maine statute becoming effective, so as to avoid becoming subject to the law. See Rachel Zimmerman & Laura Johannes, SmithKline Maine Move Finds Support, The Wall Street Journal, Aug. 7, 2000, at B6 ("Thomas Johnson, a spokesman for London-based SmithKline, says its recent decision to halt drug sales to its Maine wholesaler won't necessarily save the company money in the short term. But, he says, 'it prevents us from suffering from a law that is vague and difficult to interpret.' Mr. Johnson adds that there will be no change in availability or cost to consumers in Maine."). Because "the contours of section 2697(2)(D) are extremely vague," (Pl.'s Opp. at

15.), "economic logic . . . holds that at least some of PhRMA's members . . . are prevented from arranging the distribution channels they would otherwise prefer." (Id. at 16.) This "injury," argues PhRMA, is sufficient to render the claim ripe. (Id. at 14 (quoting Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 298 (1979) ("One does not have to await the consummation of threatened injury to obtain preventative relief. If the injury is certainly impending, that is enough."))).)

PhRMA's argument is far off the mark. Under Babbitt, PhRMA is required to "allege[] an intention to engage in a course of conduct arguably affected with constitutional interest, but proscribed by [the] statute." 289 U.S. at 298. Citing to "economic logic" and a newspaper report about a decision a manufacturer made over four years ago, and alleging that some manufacturers might desire to alter their business practices, is plainly inadequate, even under the liberal standard afforded on a Motion to Dismiss, to create a case or controversy sufficient to make this case justiciable by this Court. See id. ("The basic inquiry is whether the 'conflicting contentions of the parties . . . present a real, substantial controversy between parties having adverse legal interests, a dispute definite and concrete, not hypothetical or abstract.'"") (quoting Railway Mail Assn. v. Corsi, 326 U.S. 88, 93 (1945)). Thus, even if Judge Hornby's prior holding was not

enough, the contention contained in Count IV is clearly not ripe for review at this time.

D. Count VI -- § 1983

Because this Court finds PhRMA's other claims to be not ripe for review, PhRMA's § 1983 claim under Count VI is dismissed as moot.

E. Primary Jurisdiction Referral

Because this Court finds PhRMA's other claims to be not ripe for review, PhRMA's Motion for Primary Jurisdiction referral is Denied.

III. Conclusion

For the foregoing reasons, the Court hereby ORDERS as follows:

1. Plaintiff's Motion for Primary Jurisdiction Referral is DENIED;
2. Defendants' Motion to Dismiss Counts I, II, IV and VI of Plaintiff's Amended Complaint is GRANTED; and

3. Defendants are permanently enjoined from enforcing the provisions of Me. Rev. Stat. Ann. tit. 22, § 2697(2)(A)-(B) on the basis of out-of-state transactions.¹⁵

IT IS SO ORDERED.

William E. Smith
United States District Judge
Dated:

¹⁵ The Court previously issued a preliminary injunction in this case that prevented Maine from "seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine." PhRMA, 2000 WL 34290605, at *7. Maine does not contest this injunction. (Defs.' Mot. to Dismiss at 1.) Therefore, the Court now makes this injunction permanent.